DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

October 31, 2002

Ref: 2003-DAL-04

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Tamotsu Nakamura
President
True World Foods, Inc.
32-34 Papetti Plaza
Elizabeth, New Jersey 07207

Dear Mr. Nakamura

On September 18-19, 2002, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 8919 Governors Row, Dallas, Texas. The inspection revealed that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). Seafood HACCP information is available through links in FDA's home page at www.fda.gov.

These deviations, brought to the attention of Mr. Akifumi T. Tanimoto, General Manager, during the inspection, cause your firm to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because your seafood products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.
The deviations are as follows:

Your "all-inclusive" HACCP plan does not comply with **21 CFR 123.6(b)(2)**. You chose to group different kinds of fish and fishery products together in one plan. However, your "all-inclusive" HACCP plan attempts to group products that have different hazards e.g. pathogens, histamine, ciguatera toxin, parasites, drugs and chemicals, etc. Separate HACCP plans must be prepared when the food safety hazards, critical control points, critical limits, monitoring, verification and record keeping procedures are not identical.

Your "all-inclusive" HACCP plan does not establish the critical control points, critical limits, monitoring, verification and record keeping procedures that are specific for each food safety hazard. **[21 CFR 123.6(c)(1), (2), (3), (4),(6), and 7]**

Failure to have a plan specific to each location where fish and fishery products are processed. Your plan does not list your firm's current name and address. **[21 CFR 123.6(a)(1)]**

Failure of the most responsible individual to sign and date the HACCP plan to signify that it has been accepted for implementation. **[21 CFR 123.6(d)]**

Failure to adequately monitor and document sanitation conditions, practices and corrections during processing. **[21 CFR 123.11(b) & (c)]**

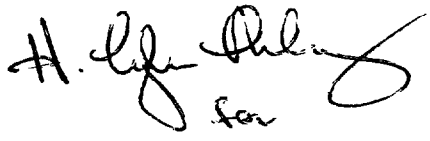
Failure to have an individual who has successfully completed appropriate HACCP training, or who is otherwise qualified through job experience, develop a HACCP plan and reassess and modify the HACCP plan in accordance with the corrective action procedures or verification activities. **[21 CFR 123.10]**

This letter may not list all the deviations at your firm. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please respond in writing within fifteen (15) working days from the receipt of this letter. Your response should outline the specific steps you have taken to correct the above deficiencies. Your reply should be addressed to the attention of Elvia J. Cervantes, Compliance Officer, Food and Drug Administration, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204.

Sincerely,



Michael A. Chappell
Director, Dallas District

MAC:ejc